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APPLICATION NO.	09/837,711	FILING DATE	04/17/2001	FIRST NAMED INVENTOR	Stephen G. Withers	ATTORNEY DOCKET NO.	UBC-P-005 - 2	CONFIRMATION NO.	1131
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21121 08/21/2002 7590  
 OPPEDAHL AND LARSON LLP  
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EXAMINER

SLOBODYANSKY, ELIZABETH

ART UNIT	PAPER NUMBER
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1652

DATE MAILED: 08/21/2002

16

# Office Action Summary

Application N .

09/837,711

Applicant(s)

WITHERS ET AL.

Examin r

Elizabeth Slobodyansky

Art Unit

1652

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 03 June 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 40-70 is/are pending in the application.
- 4a) Of the above claim(s) 51-54 and 56-70 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 40-50 and 55 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 17 April 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 14.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

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### **DETAILED ACTION**

The response filed June 3, 2002 has been entered.

The Declaration under 37 CFR 1.132 by Dr. Withers filed June 3, 2002 has been entered.

Claims 40-70 are pending. Claims 51-54 and 56-70 are withdrawn. Claims 40-50 and 55 are under consideration.

### ***Drawings***

The drawings filed concurrently with the application on April 17, 2001 have been approved by Draftsman.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 40-50 and 55 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

This rejection is reiterated from the Office action mailed November 21, 2001.

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Claims 40-50 and 55 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the use of AbgE358A for synthesizing an oligosaccharide, does not reasonably provide enablement for the same use of any other glycosidase, including  $\beta$ -galactosidase. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims.

This rejection is reiterated from the Office action mailed November 21, 2001.

### ***Double Patenting***

Claims 40-50 and 55 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-17 of U.S. Patent No. 5,716,812.

This rejection is reiterated from the Office action mailed November 21, 2001.

Claims 40-50 and 55 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1 and 2 of U.S. Patent No. 6,284,494.

This rejection is reiterated from the Office action mailed November 21, 2001.

Applicants consideration for filing a TD stated in Response filed June 3, 2002 is noted. The rejection is maintained until TD is filed.

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### ***Response to Amendment***

The Declaration under 37 CFR 1.132 by Dr. Withers filed June 3, 2002 is insufficient to overcome the 112, 1st paragraph, rejections of claims 40-50 and 55 as set forth in the last Office action because: the declaration describes results obtained after the filing date of the instant application while the 112, 1st paragraph, requirements are to be met at the time of filing.

### ***Response to Arguments***

Applicant's arguments filed June 3, 2002 have been fully considered but they are not persuasive. With regard to the written description, Applicants argue that "the written description requirement is separate from the enablement requirement, it imposes a requirement that the specification show that the Applicant really had possession of the invention as claimed as of the filing date of the application" (page 2, 1st full paragraph). The examiner agree with that. Applicants assert that "This inquiry is made based on the words in the specification. It does not depend on unpredictability in the art, but rather on whether there is a clear expression that establishes that the inventors recognized that which is claimed as their invention. In the present case, there can be no issue because the language of the specification directly parallels that which is in the claim (ibid, emphasis added). This is not agreed with because it appears that Applicants argue that just spelling out the invention is sufficient to meet the written

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description requirements. Applicants continue “where the claim at issue is substantially the same as a claim presented in the original application, there is a strong presumption that written description support exists. The Examiner has neither addressed nor overcome this presumption”(page 2, 2nd full paragraph). These arguments are not persuasive because, as mentioned above, the mere presence of the claim to the invention does not automatically render the invention sufficiently described under 112, 1st paragraph. In the present application the issue is whether the only disclosed glycosynthase, the *Agrobacterium*  $\beta$ -glucosidase E358A mutant (AbgE358A), is representative of a genus and moreover of several highly variant genera of enzymes that do not have structural similarity thereto. The examiner’s position is that the only structural limitation, i.e., the presence of two catalytically active amino acids with carboxylic acid side chains, without more is insufficient to describe the enormous number of different enzymes having no or insignificant similarity to AbgE358A that when mutated at said amino acids exhibit the requisite function.

With regard to the enablement, Applicants argue that “they only encompass glycosidase enzymes that, in the wild-type enzyme have “two catalytically active amino acids with carboxylic acid side chains within the active site”. ... the specification provides a mechanistic explanation of how the enzymatic reaction occurs, and why the claimed amino acid change results in the change of reaction type” (page 3, 2nd full paragraph). This is not persuasive because the explanation is related to the only

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example, AbgE358A. These arguments disregard any effect the rest of the enzyme structure has on the requisite mechanism of action as well as substrate, stereo- and regio-specificity. The claims encompass enzymes of different functions and the specification does not teach how the structure of enzymes other than AbgE358A relates to function. The art does not allow to predict the structure: function correlation for the enzymes that are not structurally and functionally similar to AbgE358A. In fact, no other glycosidases catalyzing the requisite reaction are disclosed in the specification or known in the art. Applicants further refer to the literature published subsequent to the effective filing date of this application (page 4). These publications are ineffective to overcome the rejection because they are published after the effective filing date of this application while the requirements must be met at the effective filing date.

### ***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the

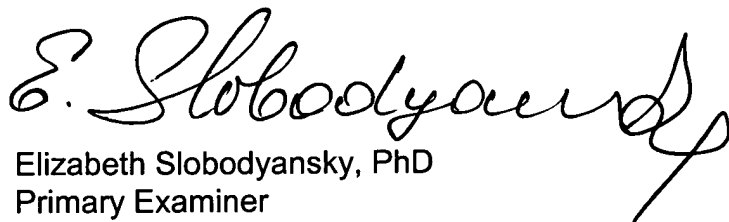
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shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elizabeth Slobodyansky whose telephone number is (703) 306-3222. The examiner can normally be reached Monday through Friday from 9:30 AM to 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Ponnathapura Achutamurthy, can be reached at (703) 308-3804. The FAX phone number for Technology Center 1600 is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Center receptionist whose telephone number is (703) 308-0196.

  
Elizabeth Slobodyansky, PhD  
Primary Examiner

August 19, 2002